OFFICE OF
CHEMICAL SAFETY AND
POLLUTION
PREVENTION

MEMORANDUM

Date: October 24, 2012

Subject: Efficacy Review for ADP
EPA File Symbol: 777-101
DP Barcode: D404022

From: Lorilyn M. Montford LM 10/25/12
Efficacy Evaluation Team
Antimicrobials Division (7510P)

Thru: Emily Mitchell, Chief EM 10/31/12
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To: Jacqueline Campbell-McFarlane/Stacey Grigsby
Regulatory Management Branch II
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Applicant: Reckitt Benckiser LLC
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, NJ 07054

FORMULATION FROM LABEL:

Active Ingredient(s)	% by wt.
Triethylene Glycol	5.40%
Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16} Dimethyl benzyl ammonium saccharinate	0.05%
Other Ingredients	94.55%
Total	100.00%

I BACKGROUND

The product, EPA Registration No. 777-101, ADP10106, is a registered non-food contact sanitizer, disinfectant, (bactericide, virucide) air sanitizer and deodorizer, for use on hard, non-porous surfaces in household locations such as bedrooms, nursery's, kitchens, laundry rooms, sunrooms and other household locations. The applicant has submitted an amendment to validate an alternate formulation for the product. The study was conducted at ATS Labs located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

This data package contained a letter from the applicant dated June 27, 2012, one study (MRID 48882303, EPA Form 8570-4 (Confidential Statement of Formula), Statement of No Data Confidentiality Claim, Good Laboratory Practice statement, and the proposed label.

II USE DIRECTIONS

The product is designed for sanitizing and disinfecting hard, non-porous surfaces, including kitchen (non-food contact) surfaces, bathroom surfaces, bed frames, desks, diaper pails, faucets, lamps, linen carts, metal blinds, shower stalls, wheelchairs, windows and door knobs. According to the label the product may be used on chrome, sealed concrete, copper, glass, glazed ceramic tile, glazed porcelain, sealed grout, marble, metal plastic, tin, stainless steel, vinyl and glazed terra cotta surfaces. Directions on the proposed label state the following for surface disinfection: Pre-clean surfaces prior to use. Shake well before each use. Hold can (container) upright 6" to 8" from surface. Spray 2 to 3 seconds until covered with mist. To disinfect, let stand for 10 (ten) minutes and allow to air dry. Directions for surface sanitization state the following: Preclean surfaces prior to use. Shake well before each use. Hold can (container) upright 6" to 8" from surface.upright (To temporarily reduce airborne odor-causing bacteria and eliminate odors, close all doors, windows, and air vents. Hold can upright, press button and spray towards the center of an average size room (12'x12'x9') for 10 seconds. For maximum effectiveness, relative humidity should be between 45% and 70%. Resume normal room ventilation after spray has settled. Repeat as necessary.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Sanitizers (For Non-Food Contact Surfaces)

The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038) Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

There are cases where an applicant requests to make claims of effectiveness against additional microorganisms for a product that is to be used as a sanitizer for non-food contact surfaces. The DSS/TSS standards are silent on this matter. Confirmatory test standards would apply. Therefore, 2 product samples, representing 2 different product lots, should be tested against each additional microorganism. Results must show bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes. Furthermore, according to information provided in Section 12.3.2 of ASTM Method E1153-94, test method for efficacy of sanitizers for non-food contact surfaces, "an average of at least 7.5 x 10^5 organisms must have survived on the inoculated control squares for the test to be valid.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 48882303 "AOAC Germicidal Spray Method" Test Organism: *Salmonella enterica* (ATCC 10708)and *Staphylococcus aureus* (ATCC 6538), for ADP 10106, by Matthew Sathe, Study Director. Study conducted at ATS Labs located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

This study was conducted against *Staphylococcus aureus* (ATCC 6538), and *Salmonella enterica* (ATCC 10708). Three lots (Lot No.'s: 1876-087&1876-088, 1876-076&1876-077, 1876-096&1876-097) of the product, ADP 10106 were tested according to the A.O.A.C. Official Method of Analysis 961.02, Germicidal Spray Method (2009 Ed.). The product was received as ready-to-use. From a stock slant, an initial tube (10 ml) of culture broth was inoculated. This culture was termed the "initial broth suspension". From this suspension, a minimum of three daily transfers using 1 loopful (10 µl) of culture into 10 mL of culture media were performed on consecutive days prior to use in testing. A 48-54 hour broth culture incubated at 35-37°C was prepared. Each test culture was vortex mixed for 3 to 4 seconds and allowed to stand for $\geq$ 10 minutes prior to use. A 0.10 mL aliquot of fetal bovine serum was added to 1.90 mL of each prepared culture to yield a 5% organic soil load. Individual glass slide carriers were each inoculated with 10.0 µL of culture using a calibrated pipettor. The inoculum was uniformly spread over the entire surface of the slide contained in a petri dish. The petri dish was covered immediately and the same procedure was repeated until all the slides were individually inoculated. For *Staphylococcus aureus*, slides were allowed to dry for 38 minutes at 35-37°C and a relative humidity of 50%. For *Salmonella enterica*, the slides were allowed to dry for 30 minutes at 35-37°C, at a relative humidity of 50%. Each lot of test substance, test carriers were sprayed in a horizontal position, at staggered intervals with the test substance for 3 seconds at a distance of 6-8 inches. Following spray treatment, each treated carrier was held at room temperature (20°C) and a relative humidity of 29% for ten minutes. At the end of the exposure time, excess liquid was drained off the carrier. Each carrier was transferred to 20 mL aliquots of Letheen Broth. All subcultures were incubated for 48$\pm$2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included those for purity, organic soil sterility, carrier sterility, neutralization subculture medium, viability and neutralization confirmation.

V. RESULTS

MRID Number	Test Organism	Batch No.	Number of Carriers	
			Exposed	Showing Growth
48882303	*S. enterica*	1876-087	10	0
	S. aureus		10	0
	S. enterica	1876-088	10	0
	S. aureus		10	0
	S. enterica	1876-076	10	0
	S. aureus		10	0
	S. enterica	1876-077	10	0
	S. aureus		10	0
	S. enterica	1876-096	10	0
	S. aureus		10	0
	S. enterica	1876-097	10	0
	S. aureus		10	0

VI. CONCLUSION

The submitted efficacy data (MRID 48882303) support the use of the product, ADP 10106, as an air sanitizer, and disinfectant with bactericidal activity against the following in the presence of a 5% organic soil load and a contact time of 10 minutes:

Staphylococcus aureus (ATCC 6538)
Salmonella enterica (ATCC 10708)

These claims are acceptable as they are supported by the submitted data.

VII. RECOMMENDATIONS

1. The proposed label claims are acceptable regarding the use of the product, ADP 10106 as non-food contact sanitizer and disinfectant for use on hard, non-food, non-porous surfaces in households for a contact time of 10 minutes, in the presence of an organic soil load.

2. Please remove the use site, "dish racks" from page 10 of the proposed label. This use-site is a food contact item.

3. On page 3 of the proposed label, please remove the term, "(healthier)" home. This term can be considered misleading.

4. On page 4 of the proposed label, please remove the phrase, "directly targets source of odors." This statement is misleading.

5. On page 4 of the proposed label, please remove the phrase, "this product destroys odors in the air… "[so odors do not come back]". This statement is misleading.

6. On pages 3 and 4 of the proposed label, "please remove the phrase, "sweeping away" from the action used to describe the product. This phrase is misleading.